

REMARKS

Claims 53-59, 67-68, 71-72 and 79-81 were pending in the application. In the Office Action dated July 20, 2005, claims 53-59, 67-68, 71-72 and 79-81 were rejected. In the instant Amendment, claims 53, 59, 67, 71 and 79-81 have been amended to clarify the invention. Upon entry of the above-made amendments, claims 53-59, 67-68, 71-72 and 79-81 will be pending.

Claim 53 has been amended to recite that the computer system is for determining a level of protein activity *in a cell of a cell type* (emphasis added). Support for the amendment can be found in the specification at page 10, lines 1-3. Claim 53 has also been amended such that each perturbation response profile comprises measurements of the same set of cellular constituents as in the diagnostic profile. Since there is no longer the need to distinguish a "first plurality" from a "second plurality", both "first" and "second" are deleted from the claims. Support for the amendment is found in the specification at page 17, line 28 through page 19, line 22; page 27, line 5 through page 28, line 18; page 30, line 18 through page 32. In particular, the specification at page 18, lines 4-21 teaches that the diagnostic profile and the response profile comprises measurements of similar aspects of the biological state of a cell. The specification at page 18, line 28 through page 19, line 7 teaches matching measurements of cellular constituents in the diagnostic profile with measurements of the same cellular constituents in the response profile. The analytic embodiments illustrate the method more clearly. For example, the embodiment described in the specification at page 30, line 18 through page 31, line 7, shows that measurement of each cellular constituent in diagnostic profile D is compared with the measurement of the same cellular constituent in the response profile R. Claims 67, 71 and 79-81 have been amended similarly.

Claim 59 has been amended to correct a typographical error.

No new matter has been added by these amendments. Entry of the foregoing amendments and consideration of the following remarks are respectfully requested.

APPLICANT'S INTERVIEW SUMMARY

Applicants thank Supervisory Examiner Ardin H. Marschel for the courtesies extended during the telephonic interview on July 9, 2005 (hereinafter "the Interview") with Mr. Weining Wang (on behalf of Ms. Adriane M. Antler). During the interview, the

Examiner informed Mr. Wang that the Amendment filed on December 22, 2004 (the "December 22 Amendment") would be entered, and that upon consideration of the December 22 Amendment, the prosecution of the present case would be reopened, with an office action forthcoming. Due to the reopening of the prosecution, the Notice of Appeal filed on December 22, 2004 is dismissed, and Applicants' burden to file a brief on appeal is obviated.

THE REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE
WITHDRAWN

Claims 53-59, 67, 68, 71, 72 and 79-81 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contends that the rejected claims contain new matter because they recite producing the interpolated perturbation response profile from a combination of first and second pluralities of cellular constituent measurements, which are also unlimited as to whether they are the same or different constituents. Applicants have amended claims 53, 67, 71 and 79-81 such that the first and second pluralities are the same plurality. The rejection of claims 53-59, 67, 68, 71, 72 and 79-81 under 35 U.S.C. § 112, first paragraph, is therefore obviated and should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 101 SHOULD BE WITHDRAWN

Claims 53-59, 67, 68, 71, 72 and 79-81 are rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. The Examiner contends that the claims are "directed to non-statutory subject matter without requiring performance of a result outside of a computer or representing some type of a physical transformation which is concrete or tangible" (Office Action at page 3, last 4 lines through page 4, line 1). The Examiner also contends that the claims are directed to non-functional descriptive material because the claims lack performance or control of a physical transformation (Office Action at page 4, lines 3-6). The Examiner further contends that the claimed methods "are reasonably deemed a manipulation of data ... without any physicality, that is, concrete or tangible, requirement ..." (Office Action at page 4, last 10 lines). Applicants respectfully disagree with the Examiner's rejection of the pending claims for the reasons presented below.

The question of whether a claim encompasses statutory subject matter should focus

on the essential characteristics of the subject matter, in particular, its practical utility. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 U.S.P.Q.2d 1596 (Fed. Cir. 1998). A claim limited to a machine or manufacture, which has a practical application in the technological arts, is statutory. Manual of Patent Examination Procedure (“MPEP”), 8th ed., rev. 2 (May 2004), at 2100-15, citing *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994). Systems and processes involving transformation of data are statutory and constitute a practical application of a mathematical algorithm, formula, or calculation if they produce a useful, concrete and tangible result. *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 U.S.P.Q.2d 1596 (Fed. Cir. 1998). A claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program or digital computer. *Diamond v. Diehr*, 450 U.S. 175 (1981). To determine whether a computer system or a process is statutory, the proper inquiry is not whether the computer system or the process manipulates data, but the significance of the data and their manipulation in the real world, i.e., *what* the computer is doing. *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 22 U.S.P.Q.2d 1033 (Fed. Cir. 1992). Claim steps employing mathematical procedures such as “converting”, “applying”, “determining”, and “comparing” are physical process steps when the steps transform one physical, electrical signal into another. *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 22 U.S.P.Q.2d 1033 (Fed. Cir. 1992). To constitute patentable subject matter under 35 U.S.C. § 101, a claim does not need to involve physical transformation since physical transformation is merely one example of how mathematical algorithm may bring about useful application, not an invariable requirement. *AT & T Corp. v. Excel Communication Inc.* 50 U.S.P.Q.2d 1447 (Fed. Cir. 1999). With respect to what is not statutory, the Supreme Court identified the following three categories of subject matter that are not patentable: laws of nature, physical phenomena and abstract ideas. *Diamond v. Diehr*, 450 U.S. 175 (1981).

Since for a Section 101 analysis regarding statutory subject matter it is irrelevant whether the claims are directed to a computer system or a computer program product, the discussion below will often be made in reference to the computer system claims. It should be understood that such discussion is equally applicable to the claims directed to computer program products.

At the outset, Applicants respectfully submit that, the computer systems or computer program products of the rejected claims are specific machines or articles of manufacture that

have a practical application in the technological arts, and therefore are statutory. Applicants respectfully submit that the Examiner erred in contending that the claimed computer systems or computer program products do not have any practical utility because they do not provide some “physicality of result or representation thereof.” The rejected claims are directed to computer systems or computer program products for determining a level of protein activity in a cell of a cell type. The computer systems transform data of measurements of cellular constituents and determine a numerical value representing a level of protein activity. Both the measurements of cellular constituents in a cell and the activity of a protein in a cell represent physical/biological aspects of cells. The determined level of activity of a protein in a cell has important technological as well as commercial uses (see, e.g., the background section of the specification, especially the disclosure at page 2, line 18 through page 3, line 24). An assertion that such claims do not have any practical utility and do not provide a useful, concrete, and tangible result is incorrect and is contradictory to the applicable case law. In *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, the court held that

... the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces “a useful, concrete and tangible result”-- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.

State Street Bank & Trust Co. v. Signature Financial Group Inc., 47 U.S.P.Q.2d 1596, 1601 (Fed. Cir. 1998) (emphasis added). In *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, which claims a method and apparatus for analyzing electrocardiograph signals to determine the presence or absence of a predetermined level of high-frequency energy in the late QRS signal, the court held that manipulation of numbers representing electrocardiograph signals related to the patient’s heart function to generate an output which indicates whether the patient is at high risk for ventricular tachycardia corresponded to a useful, concrete or tangible thing -- the condition of a patient’s heart, and, as such, constitutes a practical application. *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 22 U.S.P.Q.2d 1033, 1037-38 (Fed. Cir. 1992). Thus, if the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price and manipulation of numbers representing electrocardiograph signals related to the patient’s heart function to generate an output which indicates the condition of a patient’s heart each constitutes a practical application, transformation of data of measurements of cellular

constituents to determine a numerical value representing a level of protein activity in a cell also constitutes a practical application. If a final share price momentarily fixed for recording and reporting purposes and a numerical value indicating whether a patient is at high risk for ventricular tachycardia are useful, concrete and tangible results, a numerical value representing the activity of a protein in a cell cannot be otherwise.

The Examiner contends that the requirement of production of a useful, concrete, and tangible result is interpreted as requiring “at least some physicality or representation thereof,” and that the determining and interpolating methodology employed in the rejected claims are deemed “per se manipulations of data without any physicality, that is, concrete or tangible requirement” (Office Action at page 4, last 10 lines). The Examiner appears to interpret the requirement of production of a useful, concrete, and tangible result as a requirement of having “at least some physicality or representation thereof.” Applicants first respectfully submit that it is unclear as to what the Examiner means by the phrase “at least some physicality or representation thereof.” If the Examiner means that in order to constitute a useful, concrete, and tangible result, the result cannot be a numerical value, such a contention clearly contradicts the applicable case law. As discussed above, a final share price and a number indicating whether a patient is at high risk for ventricular tachycardia are both numerical values, but are both deemed useful, concrete and tangible results. In *State Street Bank* case, the court held that “[t]his renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.” *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 47 U.S.P.Q.2d 1596, 1602 (Fed. Cir. 1998). In *Arrhythmia* case, the court held that the fact that “the product is numerical is not a criterion of whether the claim is directed to statutory subject matter.” *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 22 U.S.P.Q.2d 1033, 1039 (Fed. Cir. 1992). If the Examiner means that in order to constitute a useful, concrete, and tangible result, there must be some useful real-world impact, then the requirement is clearly satisfied by the presently claimed computer systems and computer program products. As discussed above, the real-world impact of the claimed computer systems and computer program products is the determination of the level of activity of a protein in a cell of a cell type, which has both important technological and commercial uses.

Applicants also respectfully submit that the meaning of “useful, concrete, tangible result” has been clearly set out by the court. As is held in *AT & T Corp. v. Excel*

Communication Inc. 50 U.S.P.Q.2d 1447 (Fed Cir. 1999), a “useful, concrete, tangible result” means that the numerical result has specific meaning and is not a mathematical abstraction:

Arrhythmia's method claims satisfied Section 101 because the mathematical algorithm included within the process was applied to produce *a number which had specific meaning -- a useful, concrete, tangible result -- not a mathematical abstraction.* [citation omitted]

AT & T Corp. v. Excel Communication Inc. 50 U.S.P.Q.2d 1447, 1452 (Fed Cir. 1999) (emphasis added). Thus, the Examiner’s interpretation of the requirement of production of a useful, concrete, and tangible result is inconsistent with the case law.

Applicants respectfully submit that the Examiner incorrectly focuses on how the computer systems carry out their operations in determining whether the claims are directed to statutory subject matter. As discussed above, the computer systems of the rejected claims are for determining a level of protein activity in a cell of a cell type. The computer systems manipulate data representing measurements of cellular constituents, and determine a number representing a level of protein activity in a cell of a cell type. The fact that the claimed computer systems perform methods that involves determining perturbation levels where similarity is greatest between profiles does not automatically render the claimed computer systems non-statutory. In *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, the court held that

[i]t is of course true that a modern digital computer manipulates data, usually in binary form, by performing mathematical operations, such as addition, subtraction, multiplication, division, or bit shifting, on the data. But this is only *how* the computer does what it does. Of importance is the significance of the data and their manipulation in the real world, i.e., *what* the computer is doing.

Arrhythmia Research Technology Inc. v. Corazonix Corp., 22 U.S.P.Q.2d 1033, 1036 (Fed. Cir. 1992) (emphasis in the original). After determining that the data represent physical signals, the *Arrhythmia* court went on to hold that

[t]hese claimed steps of “converting”, “applying”, “determining”, and “comparing” are physical process steps that transform one physical, electrical signal into another. [T]he steps of Simson's claimed method comprise an otherwise statutory process whose mathematical procedures are applied to physical process steps.

Arrhythmia Research Technology Inc. v. Corazonix Corp., 22 U.S.P.Q.2d 1033, 1038 (Fed. Cir. 1992). The court also held in *Arrhythmia Research Technology Inc. v. Corazonix Corp.* that

The law crystallized about the principle that *claims directed solely to an abstract mathematical formula or equation*, including the mathematical expression of scientific truth or a law of nature, whether directly or indirectly stated, *are nonstatutory* under section 101; whereas *claims to a specific process or apparatus that is implemented in accordance with a mathematical algorithm will generally satisfy section 101*.

Arrhythmia Research Technology Inc. v. Corazonix Corp., 22 U.S.P.Q.2d 1033, 1037 (Fed. Cir. 1992) (emphasis added).

Thus, in the present case, whether the claimed computer systems are deemed “per se manipulation or conversion of data” is not determinant regarding whether the claims are statutory under section 101. The proper inquiry is what the data represent: are the data representing something having specific meaning in the real world or merely mathematical abstraction. As discussed above, both the measurements of cellular constituents in a cell and the activity of a protein in a cell are not mathematical abstractions, but represent physical/biological aspects of the cell. The claimed steps of “determining a level of perturbation” and/or “interpolating” transform data representing measurements of cellular constituents in a cell and determine a number representing the activity of a protein in a cell of a cell type, which has important technological as well as commercial uses. Therefore, the computer systems of the rejected claims are not directed to specific apparatuses that are implemented in accordance with a mathematical algorithm, and are statutory.

With respect to the Examiner’s contention that statutory subject matter requires “performance of a result outside of a computer or representing some type of physical transformation,” Applicants respectfully submit that such a contention is not supported by the case law. As discussed above, neither *State Street Bank*, which determines a final share price, and *Arrhythmia*, which determines a number indicating whether a patient is at high risk for ventricular tachycardia, involves “performance of a result outside of a computer,” but both were held statutory. In *AT & T Corp. v. Excel Communication Inc.* 50 U.S.P.Q.2d 1447 (Fed Cir. 1999), the court held that

[t]he notion of “physical transformation” ... is *not an invariable requirement*, but merely one example of how a mathematical algorithm may bring about a useful

application.

AT & T Corp. v. Excel Communication Inc. 50 U.S.P.Q.2d 1447, 1452 (Fed Cir. 1999) (emphasis added). Therefore, the case law is clear that to constitute statutory subject matter, neither performance of a result outside of a computer nor representing some type of physical transformation is required.

The Examiner also errs in contending that the rejected claims are directed to non-functional descriptive material because the claims lack performance or control of a physical transformation. As defined in the MPEP, natural phenomena, abstract ideas, or laws of nature constitute descriptive material. See Manual of Patent Examination Procedure, 8th ed., rev. 2 (May 2004), at 2100-13 and 14. In the context of computer-related inventions, descriptive material can be characterized as either functional descriptive material or nonfunctional descriptive material. *Id.* Nonfunctional descriptive material includes music, literary works and a compilation or mere arrangement of data. *Id.* Functional descriptive material consists of data structures (defined as physical or logical relationship among data elements, designed to support data manipulation functions) and computer programs which impart functionality. Functionality of descriptive material refers to *functional interrelationship with the way in which computing process are performed*. *Id.* In other words, functional descriptive material refers to data structures and programs that reside inside a computer and affect the operation of the computer, whereas nonfunctional descriptive material refers to data that reside inside a computer but do not affect the operation of the computer. As discussed in the MPEP, functional descriptive material consists of data structures and computer programs which impart functionality when employed as a computer component. *Id.* The rejected claims are not directed merely to nonfunctional descriptive material as the Examiner contends. In particular, since the rejected claims do not merely recite natural phenomena, abstract ideas, or laws of nature, they are not directed to descriptive material. Additionally, the rejected claims of the present invention are directed to computer systems (or computer program products) implementing methods for determining the level of activity of a protein in a cell of a cell type. The claimed computer systems are operated (or the claimed computer program products operate a computer system) to execute steps transforming data of measurements of cellular constituents and determining a level of protein activity. As discussed above, the rejected claims fall into the statutory subject matter under 35 U.S.C. § 101 according to applicable case law.

Therefore, Applicants respectfully submit that the rejection of claims 53-59, 67, 68, 71, 72 and 79-81 under 35 U.S.C. § 101 should be withdrawn.

THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SHOULD BE
WITHDRAWN

Claims 53-59, 67, 68, 71, 72 and 79-81 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that the phrase "said cell type" lacks clear antecedent basis. Applicants first respectfully point out that claim 80 does not contain the phrase "said cell type." The rejection is therefore not applicable to claim 80. Applicants have amended claims 53, 67, 71, 79 and 81 to recite that the computer system or computer program product is for determining a level of protein activity *in a cell of a cell type* (emphasis added). The rejection of claims 53-59, 67, 68, 71, 72, 79 and 81 under 35 U.S.C. § 112, second paragraph, is therefore obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks into the file of the above-identified application. Applicants believe that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and allowance of the application are respectfully requested.

Respectfully submitted,

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